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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,503	02/09/2001	Sanjay Sethi	11520.0228	7097

7590 11/19/2002  
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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/19/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/780,503

Applicant(s)

SETHI ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 13-20 is/are rejected.
- 7) ☒ Claim(s) 3 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.                      6) ☐ Other: \_\_\_\_\_.

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1. Claims 1-20 are pending in this application.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-11, 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsang et al (Chest/V.117/2,February 2000).

Tsang et al disclose a method for diagnosing bacteria exacerbations of chronic lung disease in a patient's sputum sample. Tsang et al disclose a method for determining the concentration of elastase in a sputum sample by reacting the sample with a chromogenic peptide substrate. Tsang et al also disclose a method for determining the concentrations of TNF- $\alpha$  and IL-8 in a sputum sample by reacting the samples with a chromogenic peptide substrate. Tsang et al disclosed that the chromogenic peptide substrate used in the method was succinyl-L-alanyl-L-alanine-p-nitroanilide. Tsang et al disclose that the methods for determining the concentration of elastase, TNF- $\alpha$  and IL-8 in the sputum samples from patients compared the color change rate of the sample to a standard color change curve. Tsang et al disclose that some of the sputum bacteria identified included *P. aeruginosa*, *H. influenzae*, *S. pneumoniae*, and *Moraxella*

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catarrhalis. Thus, Tsang et al disclose the methods claimed except for stating that the sputum sample contained lower respiratory tract secretions.

However, regarding the instant method using sputum samples containing lower respiratory tract secretions, it is noted that Tsang et al disclose and discuss results from studies covering all the patient's airway. Hence, Tsang et al disclose all the limitations claimed except for describing the sputum as a lower respiratory tract sample, but, Tsang et al disclose or address results from the study of a patient's entire airway which encompasses lower respiratory tract sputum samples.

The burden of proof is on applicant to show patentably distinct differences between the Tsang et al methods and the method claimed herein.

3. Claims 3 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The Doerschuk et al patent discloses a method for evaluating anti-IL-8 monoclonal antibodies using elastase substrate stock methoxysuccinyl-alanyl-alanyl-propyl-valyl-p-nitoranilide and has been cited to further show the state of this art.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 308-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

For 24 hour access to patent application information 7 days a week, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

  
LOUISE N. LEARY  
PRIMARY EXAMINER

November 18, 2002